

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
WESTERN DIVISION**

United States of America,

Plaintiff,

v.

Shaffer Pharmacy, Inc., et al.,

Defendant.

Case No. 3:21-CV-00022

Hon. Jack Zouhary

**BRIEF IN OPPOSITION TO MOTION  
FOR PRELIMINARY INJUNCTION**

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**PREFACE**

The simplistic numeric approach taken by the Government does not recognize why a particular provider or pharmacy may legitimately have a far higher percentage of patients needing opioids than others. First, there are many providers who are afraid of opioids because of just what has happened here. Even if they operate

legitimately, their businesses are at risk because of the perception. It is safer not to be involved with opiates which tends to send patients to pharmacies who will take the risk. Moreover, the reason people come to certain pain managers is not necessarily because the provider is operating a “pill mill.” The physicians specializing in pain management not surprisingly receive referrals of patients needing pain management from other physicians. If that pain management doctor does a good job, she will get more referrals, and news of her effectiveness will spread to others. Accordingly she will receive a disproportionate number of people who need opioids.

The same is true for pharmacies. If a pharmacist develops expertise in pain management and is able to assist doctors in developing appropriate treatments for their patients, that pharmacist will receive more referrals of such patients. And they typically will be patients who have a combination of circumstances that require fairly aggressive pain management in order to ameliorate the condition the patient suffers. Pure numbers are not the answer.

### **DISCUSSION**

But to the task at hand. To begin, the purpose of a preliminary injunction is to preserve the status quo, not grant the plaintiff affirmative relief on an interim basis. Blaylock v. Cheker Oil Co., 547 F. 2d 962 (6<sup>th</sup> Cir. 1976) and Montgomery v. Carr, 848 F. Supp. 770 (S.D. Ohio 1993). The injunctive relief sought here violates that principle.

The test for evaluating a request for a preliminary injunction is clearly set out in the jurisprudence of the Sixth Circuit. The district court is first is to consider whether a movant has demonstrated a strong likelihood of success on the merits. Next the court should turn to whether the movant would otherwise suffer irreparable injury. The third question is whether the issuance of a preliminary injunction would cause substantial harm to others. The last issue

is what is the impact on the public from the issuance of the injunction. Leary v. Daeschner, 228 F.3d 729 (6th Cir. 2000); Damon's Restaurant Inc. v. Eileen K Inc. et al., 461 F. Supp. 2d 607 (S. D. Ohio 2006); and Knapp v. Metropolitan Government of Nashville and Davidson County et al., 2020 WL 510-6761 (M. D. Tennessee 2020) [a copy of which is attached]

There is no danger of irreparable injury caused by lifting the Temporary Restraining Order and denying the Request for a Preliminary Injunction. The Shaffer Pharmacy two years ago began corrective action based on recommendations of its controlled substance wholesalers, AmerisourceBergan and Cardinal. The pharmacy reduced the number of patients served and accordingly went from 24% of patients receiving opioids to roughly 11%. It was not because there were violations, but because the distributors were too concerned about being investigated themselves that they could not run the risk for one little pharmacy in Toledo. As the Court knows, in 2017 class actions were filed against all major distributors of opioids and handled by Judge Dan Aaron Polster in Cleveland, leading to four companies paying a total of \$26 billion to resolve the claims. Both of Shaffer Pharmacy's distributors were two of the four.

As noted in the Declaration of Meredith Carter, Diversion Investigator, "(i)t is common for legitimate pharmacies to have a ratio of approximately 20% of controlled to 80% uncontrolled substances." Declaration of Meredith Carter, ¶40. The Government's Diversion Investigator goes on to note that from January to April 2020, the Shaffer Pharmacy reported 21.1% controlled to 78.9% non-controlled substance. Declaration of Meredith Carter, ¶41. In sum, Shaffer Pharmacy is now issuing prescriptions at the same rate as other pharmacies considered totally legitimate by the Government's expert.

What the injunction would do would be to prevent Shaffer Pharmacy from filling the legitimate needs of its patients. As the Court will hear, the patients cited by the Government's experts as being "abusers" were honest, hard-working people engaged in

occupations which regularly inflicted serious trauma. Still others were injured in horrific automobile accidents. Their pain is exceptional and that is why they received the dosages they did.

In the absent of the indication of improper prescribing, the injunction should fail. “The law does not require the doing of a futile act.” State of Ohio-Petitioner v. Herschel Roberts, 448 U.S. 56 (1980).

The logic of this motion for a preliminary injunction also fails because it seems to assume that the pharmacists are the initiators of the prescription process. They are not. The physician of the patient initiates the process. She or he determines what medication would be most appropriate. There is no question that the pharmacist has to evaluate the prescription to see if it is appropriate from a pharmacological standpoint, but the diagnosis and course of treatment is set by the physician. And here there have been no restrictions on them, just the pharmacists who are an important part of the safety net but secondary to the doctors.

As to the second questions, the injunctive relief so far has left many patients without access to their pain medications. Some of them have been patients at Shaffer Pharmacy for more than 40 years. The reality is that Shaffer Pharmacy had a pain management practice open up in the same building as the pharmacy, roughly 50 feet from the door. Tom Tadsen, who has operated the Pharmacy for 44 years, educated himself and his staff on what and how to insure the safety of patients and comply with the controlled substance regulations. Other pain management physicians heard about the good job Shaffer Pharmacy was doing and sent their patients there. The pharmacists came to know the referring doctors and their practices. They became confident that their physicians were not writing improper prescriptions.

Only the doctors and the pharmacists have talked with the patients. It does not appear that anyone from the Government has had any interaction with the actual patients. Nor did they have any interaction with the owners of Shaffer Pharmacy. As noted, Tom Tadsen has operated this pharmacy for over 40 years without incident. Likewise Dr. Wilson Bunton has been there for five years and Mr. Tadsen will tell you he is one of the brightest pharmacists he knows.

The reality is that the injunction did not alleviate any of the patients' pains. On the contrary, the TRO, as will be pointed out, caused the patients' access to their essential medications has been cut off. Those men and women continue to hurt every day as they have in the past, it is just that now they do not have access to the Shaffer Pharmacy to fill those scripts. You will learn that having them tagged as patients who caused Shaffer Pharmacy to be shut down because of the filling their prescriptions does not make them a desirable patient for other pharmacies.

It is significant that there is legitimate concern at the Federal level for the tendency of others, including doctors and insurers, to stigmatize persons who need long-term opioid care. See *Pain Management Best Practices, Final Report of a Committee of the Department of Health and Human Services USA*, a portion of which is attached as Exhibit 2. The articles makes suggestions as to steps that can be taken to reduce the problem of stigmatization. This is precisely the problem that was created for the legitimate patients of the Shaffer Pharmacy when the Temporary Restraining Order in this case issued.

There also is a concern here expressed by the Center for Disease Control and Protection. An immediate statement issued April 24, 2019, the CDC advised against misapplication of the Guideline for Prescribing Opioids for Chronic Pain. For example, this message states:

“Examples of misapplication include applying the guideline to patients in active cancer treatment, patients experiencing acute sickle cell cases or patients experiencing post-surgical pain.”

It further cautions against:

“The guideline does not support abrupt tapering or sudden discontinuance of opioids. These practices can result in severe opioid withdrawal symptoms including pain and psychological distress, and some patients might seek other sources of opioids. In addition, policies that mandate hard limits conflict with the Guideline’s emphasis on individualized assessment of the benefits and risks of opioids given the specific circumstances and unique needs of each patient. “

The statement also observed the following:

“The Guidelines state, when opioids are started a clinician should prescribe the lowest effective dosage. Clinicians should...avoid increasing dosage to a 90 MME/day or carefully justify a decision to titrate dosage to a 90 MME/day.” The recommendation statement does not suggest discontinuance of opioids already prescribed at higher dosages.” See Exhibit 3.

To be sure, defendants are aware of the opioid crisis. This why they have chosen to develop an expertise in that field to be sure they were doing their job properly. You will find that many of their referring physicians have contracts with their opiate patients. These contracts require regular urine screenings and pill counts. The consequence of not honoring the contract is that patient will be terminated by the doctor. The fact is that the pill counts are performed by Shaffer Pharmacy. A pill count occurs from time to time when the referring physician will want to make sure patients are taking their medications as ordered. The doctor will notify the patient that he or she is to go to Shaffer Pharmacy with their pills that day and let the pharmacist count the number of pills they have. It is done this way because the pharmacists know what the pills look like and can determine if the pills being counted are in fact what is prescribed. They then report the number of pills to the doctor who can decide whether the utilization has been appropriate or not.

The two pharmacists certainly know of the opiate crisis, as noted, but they also know that the majority of the problems come from street drugs, not from prescriptions. There is no indication in anything filed by the Government that there is actual diversion going on, meaning that patients are selling their drugs to somebody else.

Moreover, the economic impact on Shaffer Pharmacy is devastating. It is not just the pain meds that their patients buy. When they come in to get their pain medications, they buy all their other medications and so the income from the opiates may be small but the impact of the loss of those patients is staggering. It frankly threatens the existence of that pharmacy.

The Government's need for a TRO and now an injunction is hard to understand. All the pharmacy's purchases of drugs are monitored. Inventories are taken regularly by the State and match up against what has been sold and what is left. So there cannot be any disposal of drugs without a clear record. Second, as noted in the Government's papers, the OARRS system allows state regulators to monitor all of the opiate prescriptions written by Shaffer Pharmacy. In short there is a trail which can easily be followed which is beyond the ability of Shaffer Pharmacy to change. As to a point raised by the Government, the fact is that the pharmacists at Shaffer Pharmacy review most of the patients' OARRS report once a month, not the required once a year.

In another point not apparently known to the Government, the Shaffer Pharmacy works to wean patients off their opiate medications if the physician wants that. They stock opiates which are manufactured in such a way that they can only be taken orally as prescribed. They are more expensive and many insurers will not pay for them but these versions cannot be grounded up "to be shot in the arm or sniffed up the nose." They carry these specialty formulations for just that reason.

When the evidence is all in, Defendants believe their operation of their pharmacy will be shown to have been exemplary. Do they have more opiate sales than other area pharmacies? Certainly. That is the business model they set up. In 2019, they had to change their business model because their main distributor expressed concern about the volume of opiates being sold. They did not match up against other pharmacies in the area. Mr. Tadsen tried to explain to the distributor that it was a result of a conscious choice of a way to operate his business. But the distributor reported that it had been sued 2,800 times in the previous year over opiate use and it simply was not going to run the risk. It cut them off.

Shaffer Pharmacy found another distributor who agreed to supply them but asked that they reduce the number of patients they were serving and Shaffer did. In fact in 2020 it cut the number of patients being sold opiates in half. At present a little over 11% of the customers are receiving opiate. That is not yet another reason that injunctive relief is simply not necessary.

Further proof that the TRO and injunction are not necessary comes from an action filed by the Government on December 22, 2020 against Walmart and its 5,000 pharmacies. United States of America v. Walmart Inc., et al., 20-CV-1744, United States District Court for the District of Delaware. The allegations of the 160 page complaint are quite similar to those here, with the additional issue that Walmart also serves as its own distributor. Was there any interim injunctive relief sought in that case - NO. All 5,000 pharmacies, including three in Toledo, continue to distribute opiates just as they did before. There was never a break in service. Perhaps Walmart is simply too big to be enjoined. But by putting the Shaffer Pharmacy out of the opiate business, the result is that their patients will go to Walmart or to pharmacists less skilled in handling pain medication and thus put themselves at a bigger risk.



Dr. Carl Gainor in his Declaration noted that some patients pay with cash for some drugs while having insurance pay for the same drug. The explanation is simple and certainly should have been known by Dr. Gainor. Many insurers limit the number of opioid capsules they will provide each month for a patient. Someone may need to take 90 opiate products a day to be able to function and yet the insurance company will only pay for 60. The alternative is for the patient to suffer or reach into his own pocket to pay cash for the remaining 30 needed to complete his care.

### **CONCLUSION**

In balancing the harm to the Shaffer Pharmacy, its customers and the public, the Government is causing them to suffer significantly with no real benefit from the issuance of injunctive relief. Accordingly the request for a preliminary injunction should be denied.

Respectfully submitted,

/s/ Richard M. Kerger  
*Counsel for Defendants,*  
*Shaffer Pharmacy, Inc. and Thomas Tadsen*

/s/ Charles M. Boss  
Counsel for Defendant Wilson Bunton

### **CERTIFICATE OF SERVICE**

This is to certify that a copy of the foregoing has been electronically filed this 21<sup>st</sup> day of January, 2021. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's System.

/s/ Charles M. Boss